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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,478	02/23/2004	Paul Haefner	GUID.606PA	1794
51294	7590	12/07/2005		EXAMINER
HOLLINGSWORTH & FUNK, LLC				KAHELIN, MICHAEL WILLIAM
8009 34TH AVE S.				
SUITE 125			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55425			3762	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/784,478	HAEFNER, PAUL
	Examiner	Art Unit
	Michael Kahelin	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 November 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
 4a) Of the above claim(s) 20-29 and 37-48 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-19 and 30-36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02232004; 06/01/04</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-19 and 30-36 in the reply filed on 11/18/2005 is acknowledged. The traversal is on the ground(s) that inventions I and II are not distinct because the separate utility of the subcombination is hypothetical and without foundation. This is not found persuasive because the manipulating the signal without separating the cardiac signal will result in a separate utility; namely an invention that detects that a heartbeat is present, but does not separate the signal, thus decreasing the computational requirements. Additionally, the traversal is on the ground(s) that inventions I and III are not distinct because the separate utility of the subcombination not a viable example, but only a difference in claimed features. This is not found persuasive because the subcombination, which does not use time windows, is less computationally intensive, thus providing a separate utility. Finally, the traversal is on the ground(s) that inventions II and III are not distinct because the method of group III could include detection in a thoracic location. This is not found persuasive because, while the signal could be detected in a thoracic location in group III, the signal is required to be detected in a non-intrathoracic location in group II. Only one-way distinctness is required in process/apparatus claims and the method of group III could be performed with another apparatus (namely one having intrathoracic electrodes).

The requirement is still deemed proper and is therefore made FINAL.

2. In response to Applicant's assertion that groups III and I, claims 1-19 are erroneously restricted on the grounds of process/apparatus, the argument is persuasive. However, the groups are still distinct, and restriction proper, based on the justification above.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4, 7-11, 16-18, 30, 32-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht et al. (US 5,704,365 hereinafter "Albrecht") in view of Turcott (US 6,409,675 hereinafter "Turcott"). Albrecht discloses the essential features of the claimed invention including:

5. In regards to claims 1 and 30, Albrecht discloses detecting a composite electrical signal (abstract and col. 2, line 20), receiving information related to a non-electrophysiological source (col. 30, line 42), separating a signal from the composite signal (col. 4, line 30), and identifying the signal as a cardiac signal based on the signal and the non-electrophysiological information. Examiner is interpreting "identifying the signal as a cardiac signal" as filtering out noise.

6. In regards to claim 8, the information is pulse pressure information (col. 30, line 51).

7. In regards to claims 11, 32 and 33, a detection window is provided (210) with a start time (col. 14, line 27).
8. In regards to claim 36, cardiac rhythms are discriminated (col. 13, line 44).
9. Turcott does not disclose detecting the signals in a subcutaneous non-intrathoracic location, sensing acoustic information, sensing blood flow information, sensing pulse oximetry information, sensing transthoracic impedance, detecting a cardiac condition using the separated signal, detecting a cardiac condition using a correlation between the separated signal and the other signal, and detecting arrhythmia using the signal. Turcott teaches of detecting signals in a subcutaneous intrathoracic location to avoid invasive intravascular surgery (col. 3, line 6), sensing acoustic information (which is blood flow information) to provide information of the heart's mechanical performance (col. 16, line 9), sensing pulse oximetry information to provide pulmonary information (abstract), sensing transthoracic impedance to determine breathing patterns (abstract), and detecting arrhythmia (via heart rate variability analysis) using the separated signal and a correlation between the separated signal and a non-electrical source to accurately diagnose heart abnormalities (col. 7, line 33). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Albrecht's invention by detecting signals in a subcutaneous intrathoracic location to avoid invasive intravascular surgery, sensing acoustic information (which is blood flow information) to provide information of the heart's mechanical performance, sensing pulse oximetry information to provide pulmonary information, sensing transthoracic impedance to determine breathing

patterns, and detecting arrhythmia (via heart rate variability analysis) using the separated signal and a correlation between the separated signal and a non-electrical source to accurately diagnose heart abnormalities.

10. Claim 2, 3, 5, 6, 12, 13, 19, 31, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht in view of Turcott, as applied to claim 1 above, and further in view of Corbucci (US 6,792,308 hereinafter “Corbucci”). The modified invention of Albrecht discloses the essential features of the claimed invention except for providing a window defined by the non-electrical signal, detecting a QRS complex within the window, utilizing the temporal location of the peak heart sound, defining the start of detection window based in a time preceding the peak heart sound, determining a time separation between a peak of the separated signal and a peak of the non-electrical signal, and treating arrhythmia. Corbucci teaches of defining a window with heart sounds (PEI+ET, Fig. 5) to electrical activity in comparison to electrical activity, detecting a QRS complex within the detection window (152) to accurately determine time intervals between electrical activity and sounds, utilizing the temporal location of the peak heart sound (s1) to accurately determine intervals between sounds and electrical activity, defining the start of detection window based on a time preceding the peak heart sound (PEI) to calculate the myocardial performance, determining a time separation between a peak of the separated signal and a peak of the non-electrical signal (PEI) to determine the degree of heart failure, and treating arrhythmia (143) to prevent heart stoppage. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified invention of

Albrecht by defining a window with heart sounds to electrical activity in comparison to electrical activity, detecting a QRS complex within the detection window to accurately determine time intervals between electrical activity and sounds, utilizing the temporal location of the peak heart sound to accurately determine intervals between sounds and electrical activity, defining the start of detection window based on a time preceding the peak heart sound to calculate the myocardial performance, determining a time separation between a peak of the separated signal and a peak of the non-electrical signal to determine the degree of heart failure, and treating arrhythmia to prevent heart stoppage.

11. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht in view of Turcott, as applied to claim 1 above, and further in view of Wells (US 2003/0032889 hereinafter "Wells"). The modified invention of Albrecht discloses the essential features of the claimed invention except for separating signals using blind source separation and independent component analysis. Wells teaches of identifying constituent signals using blind source separation and independent component analysis (par. 0007) to separate signals where little is known of their individual contributions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modify the modified invention of Albrecht by identifying constituent signals using blind source separation and independent component analysis to separate signals where little is known of their individual contributions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



GEORGE R. EVANISKO
PATENT EXAMINER
2/4/15